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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/826,420
Filing Date: April 05, 2001
Appellant(s): MCGOWAN,, JAMES E.

Mark J. Henry
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed on 08/19/2005 appealing from the Office action mailed on 12/29/2004.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

Claims 1, 4-7, 15, and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGowan, Jr. (U.S.P.N. 5,749,203).

Claims 2-3, 8-14, 16-17, and 22-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGowan, Jr. (U.S.P.N. 5,749,203) in view of Multivac Packing Machines (IDS).

Withdrawn Rejection

The 35 USC 112, first and second paragraphs rejections with respect to claim 33 applied in the final action dated on 12/29/2004 have been withdrawn.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,749,203 McGowan, Jr. 5-1998

Multivac Packing Machines, "Pin Gas Flushing System for Uniform Gas Distribution", 1998

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 4-7, 15, and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGowan, Jr. (U.S.P.N. 5,749,203).

With respect to claims 1 and 15, the McGowan reference discloses a device (figure 1, 10) and a method (col.1, lines 5-9) for article sterilization. Further, the McGowan reference teaches the following: a device to form a housing in a first web (col.3, lines 27-29), an article loading station (col.3, lines 25-27), an alignment device (col.3, lines 38-42), a sterilization-sealing station for sterilizing a medical article inside the housing (col.3, lines 53-55), and sealing the medical article within the housing (col.4, lines 5-9). In addition the McGowan reference teaches that it is known in the art of sterilizing medical articles to precondition such articles in a pretreatment area by applying steam (col.1, lines 28-34) prior to sterilizing them. Thus, it would have been

obvious to one having ordinary skill in the art to modify the method and the apparatus of the McGowan reference to include a preheating step since such a step results in increasing the sterilizing effects of ethylene oxide (col.1, lines 36-44).

With respect to claims 4-5 and19, the McGowan reference discloses the following: the sterilization-sealing station includes a steam source (col.3, lines 38-46), it is known in the art that substantially no moisture is supplied to the medical articles at the sterilization-sealing station (col.2, lines 42-58), and the pretreatment area has a steam supply (col.1, lines 28-33).

With respect to claims 6-7 and 20-21, the McGowan reference discloses the following: it is known in the art for the sterilization-sealing station includes a vacuum (col.1, lines 50-53) and a controller such that a controller is known in the art to be intrinsic to maintain the pressure in the housing (col.1, lines 52-53). In addition, in the art it is known that a controller is intrinsic to maintaining the pressure in the housing as to allow the relative humidity to be at least 40% during sterilization gas exposure (col.2, lines 57-67).

With respect to claim 18, the McGowan reference discloses injecting steam into the housing (col.10, lines 61-64).

Claims 2-3, 8-14, 16-17, and 22-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGowan, Jr. (U.S.P.N. 5,749,203) in view of Multivac Packing Machines (IDS).

With respect to claims 8, 22, and 33, the McGowan reference discloses a device (figure 1, 10) and a method (col.1, lines 5-9) for article sterilization including the

following: a device to form a housing in the first web (col.3, lines 27-29), an article loading station (col.3, lines 25-27), an alignment device (col.3, lines 38-42), a sterilization-sealing station where the article is sterilized by injecting gas between the first and second webs using injection nozzles (figure 4D), and then sealing the housing (col.4, lines 5-9). However, the McGowan reference fails to teach injecting gas by using pins. The disclosure of the Multivac Packing Machines reference teaches injection by using pins (advantages column). Thus, it would have been obvious to one having ordinary skill in the art to modify the McGowan reference method and device to include gas injection pins in order to eliminate small cracks between webs of film where air can enter packages along with gas are eliminated (column 1, lines 5-10).

The features of claims 2, 16-17, 23, and 35-36 have been addressed above with respect to claims 8, 22, and 33.

With respect to claims 3, 9, and 24, the McGowan reference teaches injecting steam into the housing between the first and second webs (figure 4D and col.10, lines 52-53) and the injected steam pressurizes the housing to a pressure of 60 to 100 Psia (col.10, lines 54-55).

With respect to claims 10 and 29, the McGowan reference discloses that it is known in the art of sterilizing medical articles to have a pretreatment area for heating such articles (col.1, lines 28-33).

With respect to claims 11 and 28, the McGowan reference teaches that both the bottom and the top webs are formed of a gas permeable material (col.3, lines 29-31).

With respect to claim 12, the McGowan reference teaches the following: it is known in the art that substantially no moisture is supplied to the medical articles at the sterilization-sealing station (col.2, lines 42-58) and the prior art teaches that the pretreatment area has a steam supply (col.1, lines 28-33) to supply moisture to the medical articles.

With respect to claims 13-14, the McGowan reference discloses the following: it is known in the art that the sterilization-sealing station includes a vacuum (col.1, lines 50-53) and a controller such that a controller is intrinsic to maintain the pressure in the housing (col.1, lines 52-53). In addition, it is known in the art that a controller is intrinsic to maintaining the pressure in the housing as to allow the relative humidity to be at least 40% during sterilization gas exposure (col.2, lines 57-67).

With respect to claim 25, the McGowan reference teaches evacuating the housing before pressurizing with steam (figure 4C). With respect to evacuating the housing after pressurizing with steam, the McGowan reference teaches that after removing the supply of steam then the sterilizing gas is introduced (col.10, lines 64-65). However, since the housing is not sealed yet; removing the supply of steam would inherently result in steam moving out of the housing and in reducing the pressure within the housing.

With respect to claim 26, even though the McGowan reference does not explicitly teach of a time period of maintaining the housing with steam, certainly some time interval is needed to reach the specified steam pressure within the housing (col.10, lines 62-64).

With respect to claim 27, the McGowan reference teaches pressurizing the housing with steam and with sterilizing gas within a form, fill and seal device (10) having sterilization–sealing station (410). With regard to the Btu values, even though the McGowan reference does not explicitly discloses such values, however, the McGowan reference pressurizes the housing with steam to a pressure of 80 Psia such that the McGowan reference is delivering energy that falls within the Btu value range.

With respect to claims 30-32, the McGowan reference discloses the following: it is known in the art that sterilization and sealing are conducted at a sterilization-sealing station (col.2, lines 42-58), the sterilization-sealing station includes a steam source (col.3, lines 38-46), it is known in the art that substantially no moisture is supplied to the medical articles at the sterilization-sealing station (col.2, lines 42-58), the pretreatment area has a steam supply (col.1, lines 28-33), it is known in the art that the sterilization-sealing station includes a vacuum (col.1, lines 50-53), it is known in the art to maintain the pressure in the housing (col.1, lines 52-53), and it is also known to maintain the pressure in the housing as to allow the relative humidity to be at least 40% during sterilization gas exposure (col.2, lines 57-67).

The features of claim 34 have been addressed above with respect to claims 1 and 15.

(10) Response to Argument

Issue 1

On page 11 of the brief, appellant argues that, "This portion of the reference indicates that a preconditioning phase was used on a once-had belief that ethylene oxide gas performed better at elevated temperatures."

It is not believed that the past tense ("thought to be") was used to indicate that the science and/or concept was wrong, but only to indicate that the science and/or concept was used previously, i.e., in the past. Even if the prior concept may have been in error, it does not detract from the fact that other types of pretreatment achieve a better result if only by cumulative effect.

Issue 2

On page 11 of the brief, appellant argues that, "This portion of the reference indicates that the chamber sterilization process is problematic because they require too much time. In the final office action, the examiner states "the phrase too much time" is a subjective term that varies from one person skilled in the art to another and is not a teaching applying neither [sic.] the pretreatment concept nor a drawback." This is not correct. If the '203 patent stated that the process required five hours, it would be subjective whether five hours are not enough time, the correct amount of time or too much time. The '203 patent goes beyond stating a time. The '203 patent teaches that the chamber sterilization process requires too much time. Clearly, this is not a compliment. It does not matter that people might disagree with whether too much time is required. The important thing is what did the author of the '203 patent think. The author of the '203 patent thought this was a "drawback."

With respect to "too much time", it is believed that this is not a negative teaching. Only that those applicants wanted a shorter time period. In achieving this shorter period, they were willing to forgo the advantage of having the pretreatment. Although with the pretreatment one would expect better overall sterilization (if only by cumulative effect) if one was willing to forgo the benefit that flow from the pretreatment step.

Issue 3

On page 13 of the brief, appellant argues that, "On the other hand, the '203 patent is directed to a very different application, namely sterilization of medical articles."

The Multivac reference is a part of a form-fill-and seal device as in the instant application such that insuring that air does not enter into packages by substituting one injection means for another would have been obvious to one having ordinary skill in the art of sterilization.

Issue 4

On page 13 of the brief, appellant argues that, "Alternatively, does the examiner propose to use the pins instead of the nozzle 446? If the examiner proposes to eliminate the nozzle 446, where is the motivation for doing this."

The examiner's motivation statement is that it would have been obvious to one having ordinary skill in the art to modify the McGowan reference method and device to include gas injection pins in order to eliminate small cracks between webs of film where air can enter packages along with gas are eliminated (column 1, lines 5-10). The phrase " to including gas injection pins" means to use the pins instead of the nozzle 446.

Issue 5

On page 14 of the brief, appellant argues that, "One having ordinary skill in the art would certainly not think that gas injection pins would solve any supposed sealing problem."

The Multivac reference recognizes in col.1, lines 5-10, that the presence of small cracks between webs is a problem in the art of designing form-fill-and seal devices that one having ordinary skill in the art would use gas injection pins since the pins are totally inside the sealing die.

Issue 6

On page 14 of the brief, appellant argues that, "It does not appear that positioning many gas injection pins between the two webs, instead of positioning a single ported nozzle between the two webs would solve a supposed crack problem."

The Multivac reference teaches in col.1, lines 13-15, that any number of gas injection pins can be used. This teaching includes a single gas injection pin. Clearly, whether one or multiple gas injection pins are used, having pins that are totally placed inside the sealing die eliminates the crack problem.

Issue 7

On page 14 of the brief, appellant argues that, "The text referring to the elimination of gas is not understood. Does it mean that the elimination of gas is good or that the elimination of gas is bad?"

The Multivac reference insures that outside contaminated air does not enter the internal sterile medium of packages and that only flushing gas from a cylinder does. The purpose of the Multivac reference is to maintain sterility of the packaged items.

Issue 8

On page 15 of the brief, appellant argues that, "If switching from a ported nozzle to gas injection pins would slow the dissipation of ethylene oxide and lengthen the time required for the process, then the '203 patent teaches away from the substitution."

The Multivac reference was combined with the McGowan reference for preventing contaminated air to enter the internal volume of packages along with intended gases and not for lengthening the time of ethylene oxide gas dissipation step.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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Au 1744
October 26, 2005

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